An Introduction to the Regulation of Prescription Drug Promotion: The Role of FDA

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Presentation Overview

- Introduction to FDA and DDMAC
- Regulatory authority
- Regulatory requirements
- Evolution of Direct-to-Consumer advertising
- Advertising examples
- DDMAC enforcement, policy, advisory, surveillance and research programs

An Introduction to FDA and DDMAC

Agencies and Offices within Department of Health and Human Services

- OS – Office of the Secretary
- ACF - Administration for Children & Families
- AoA - Administration on Aging
- AHRQ - Agency for Healthcare Research & Quality
- ATSDR - Agency for Toxic Substances & Disease
- CDC - Centers for Disease Control & Prevention
- CMS - Centers for Medicare & Medicaid Services
- FDA - Food & Drug Administration
- HRSA - Health Resources & Services Administration
- IHS - Indian Health Service
- NIH - National Institutes of Health
- OIG - Office of Inspector General
- SAMHSA - Substance Abuse & Mental Health Services Administration

FDA

What does FDA do?

- FDA is responsible for:
  - protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, and products that give off radiation
  - regulating tobacco products
  - advancing the public health by helping to speed product innovations
  - helping the public get the accurate, science-based information they need to use medicines and foods to improve their health

DDMAC's Mission

- Protect the public health by assuring prescription drug information is truthful, balanced, and accurately communicated

- To guard against false and misleading advertising and promotion through comprehensive surveillance, enforcement, and educational programs

DDMAC's Role

- Surveillance and enforcement
- Advice to industry/within FDA
- Guidances and policy development
- Research

FDA's Regulatory Authority Regarding Promotion

Regulatory Authority

- Federal Food, Drug and Cosmetic Act
  - Prescription drug promotion **must**...
    - Not be false or misleading
    - Have fair balance
    - Be consistent with the approved product labeling, or the package insert (PI)
    - Only include claims substantiated by adequate and well-controlled clinical studies

False, Lacking in Fair Balance or Otherwise Misleading

"Contains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective…safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence…whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations or references." (21 CFR 202.1 (e)(5)(i))

"Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective … by substantial evidence or substantial clinical experience." (21 CFR 202.1 (e)(5)(ii))

What Does this Mean?

- Accurately communicate indication(s) including context for any claim
  - Limitations on indication(s)
    - Relevant patient population
    - Concomitant therapies/treatments
  - Likelihood of benefit(s)
- Communicate most important risks in a manner reasonably comparable to benefits (presentation and language)
- Cannot omit important information

- In plain language → Ads must communicate an accurate and balanced picture of the drug product

Regulatory Authority

- **Code of Federal Regulations (CFR)**
  - **202.1 - Prescription Drug Advertising**
  - **312.7 - Preapproval Promotion**
  - **314.550 - Subpart H, Accelerated Approval for Drugs**
  - **601.40 - Subpart E, Accelerated Approval for Biologics**

Title IX of FDAAA – DTC provisions

- Sec. 901 of Title IX of FDAAA contains a number of provisions related to DTC advertising:
  - Prereview of DTC TV ads (adds § 503B to FDCA)
  - Clear, conspicuous, and neutral manner major statement requirement (amends § 502(n) of FDCA)
  - Civil monetary penalties for violative DTC ads (amends § 303 of FDCA)
  - Report on DTC advertising
- Sec. 906 of Title IX - Statement for Inclusion in DTC Drug Ads

Regulatory Authority

- Post-Approval Regulations located in 21 CFR 314.81(b)(3):
  - Require the submission of all promotional materials at the time of initial dissemination or publication
  - Must include Form FDA 2253 and current PI
  - DDMAC receives >70K submissions per year

Clarification to Some Beliefs

- Preapproval or preclearance
  - Law prohibits requiring preapproval of any ad except under "extraordinary circumstances"
- Types of Reviews
  - Enforcement
    - Review process for materials already in use
      - Submitted materials
      - Monitoring program
  - Advisory comments
    - When requested by sponsors
      - Launches, TV ads, other materials
    - Pre-submission
      - Accelerated approval (subparts E and H)

Categories of Promotional Materials

- Labeling
  - Audio, video, or printed matter (e.g., brochures, booklets, mailing pieces, exhibits, slides)
  - Supplied or disseminated by the manufacturer, distributor, packer, or any party acting on behalf of the sponsor
  - Accompanied by the approved product labeling
- Advertising
  - Advertisements in published journals, magazines, newspapers, and other periodicals
    - Accompanied by a “Brief Summary” of the approved product label
  - Broadcast (e.g., TV, radio, telephone communication systems)
    - Accompanied by a “Brief Summary” of the approved product label OR discloses the most important risk information and makes “Adequate Provision” for disseminating the approved product label

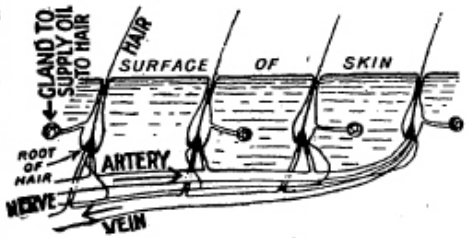
Advertising: FDA versus FTC

- FDA – created in 1906
  - Prescription drugs (human and animal)
  - Restricted medical devices
  - Biologics
  - Vaccines
  - Tobacco **new**
- FTC – created in 1914
  - Over-the-counter drugs
  - Unrestricted medical devices
  - Dietary supplements
  - Consumer package goods
  - Tobacco

Why regulate prescription drug advertisements?

FALLING OUT HAIR PREMATURELY GREY

CAN BE CURED BY TAKING CAPSULOIDS.



LOOK AT THIS PICTURE OF THE SKIN and you can plainly see how the hair grows, also that nothing rubbed on the skin or hair can ever get down to enter the roots. The hair can be made to grow firm again and the colour restored only through the roots, and by taking **CAPSULOIDS.**

DOSE.—2 or 3 just before each meal, three times daily.

18, Stanbridge Road,
Putney, S.W.

Gentlemen,—I cannot thank you enough for sending me your little Hair booklet, for that caused me to try Capsuloids for my hair, which was falling out so rapidly that I feared I would lose it altogether; and so much had fallen out that I had been using a wig for six weeks.

I enclose my photograph, which I have just had taken, so that you may see how splendid my hair now is.

My hair was formerly of a very light colour, and it was considered very beautiful, and it is now even more beautiful, for it is almost golden—that is, a richer colour.

If Capsuloids were a guinea a box I would not be without them. I have taken many boxes, but I am repaid a thousandfold.

Gratefully yours,
Mrs. F. OTTO PASSMORE.

MRS. F. OTTO PASSMORE

SCIENCE and the MICROSCOPE HAVE PROVED that when a certain peculiar germ settles in the growing cells in the tips of the hair-roots, those roots become weakened and stop carrying up the colour from the blood corpuscles to the hair, and often become loose, so that the hair falls out.

WE GUARANTEE THAT **CAPSULOIDS** Will Kill those Germs,
WE GUARANTEE THAT Will then Restore the Hair.

Capsuloids contain those wonderful little blood corpuscles extracted from the purest fresh blood, specially treated, and enclosed in little gelatine covers. They agree with the weakest stomachs. They produce millions of new red corpuscles which kill the germs, strengthen the roots, and make them grow firm again, supply more colour, which the roots carry up to the hair, and make the hair once more grow luxuriantly.

SEND FOR FREE HAIR BOOKLET AND COPY OF WHAT THE "LANCET" SAYS.

Sold everywhere at the reduced price of **2/3** per box, or sent post free by the **Capsuloid Co., Ltd., 31, Snow Hill, London, E.C.** (B. & W.). Special free sample given when three boxes are ordered, larger sample with six, if this Coupon is enclosed.

CARBOLIC SMOKE BALL

WILL POSITIVELY CURE

COUGHS	CATARRH	HOARSENESS	THROAT DEAFNESS	INFLUENZA	CROUP
COLD IN THE HEAD	ASTHMA	LOSS OF VOICE	BRONCHITIS	HAY FEVER	WHOOPING COUGH
COLD ON THE CHEST	BRONCHITIS	SORE THROAT	SORE EYES	HEADACHE	NEURALGIA

As all the Diseases mentioned above proceed from one cause, they can be Cured by this remedy

£100 REWARD

WILL BE PAID BY THE

CARBOLIC SMOKE BALL CO.

INFLUENZA,

£1000 IS DEPOSITED

THE CARBOLIC SMOKE BALL,

TESTIMONIALS.

SIR MORELL MACKENZIE, M.D.,

H.I.M. THE GERMAN EMPRESS.

TESTIMONIALS.

The Originals of these Testimonials may be seen at our Consulting Offices, with numerous others.

One CARBOLIC SMOKE BALL will last a Family several months, making it the cheapest remedy in the world at the price—10s. post free.

The CARBOLIC SMOKE BALL can be refilled when empty, at a cost of 5s., post free. Address:

CARBOLIC SMOKE BALL CO., 27, PRINCES ST., HANOVER SQ., LONDON, W.

Categories of Promotional Materials

Help-Seeking/
Disease Awareness
Institutional
Reminder

Product Claim

Cannot make any representations about a specific product - requires no balance

Types of Prescription Drug Advertising

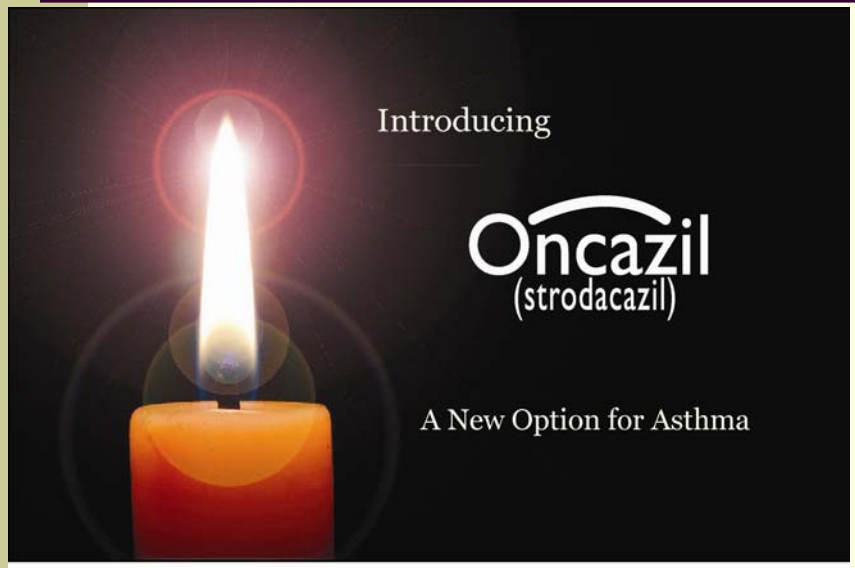
- Help Seeking/Disease Awareness- discussion of disease
- Reminder- names the drug but does not include indication, dosage recommendations, or any other non-permitted representations about the drug
- Product Claim- must include information about the drug in “brief summary”

Regulatory Requirements

In Brief Summary: Risk Disclosure for Print Ads

- Print ads need information "in brief summary" about risks and effectiveness
  - Risk presentations comparably prominent to effectiveness presentations as "fair balance"
- Regulations require that print ads must address **all** risk concepts
  - Draft Guidance provides alternatives to traditional "brief summary" for DTC print ads
    - Approved PPI
    - Consumer friendly version of risks from Highlights

Example of Print Ad Brief Summary



A New Option for YOU

Are you looking for a new way to help control your asthma? Ask your doctor if prescription Oncazil is right for you!

Oncazil is a new treatment for asthma problems that you take only once a week.

Now you don't have to think about taking a pill every day. Leave that nagging feeling behind for the entire week!

Oncazil is generally safe and effective.
Clinical trials have shown that it helps provide safe and effective asthma symptom control. Individual results may vary.

Important Information:
Oncazil will not replace fast-acting inhalers for sudden symptoms. If you get an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks. In rare cases, Oncazil may cause serious heart valve problems that begin with a noticeable change in heart rhythm. Also, in rare cases, Oncazil may cause a mild and temporary skin sensitivity to heat. If it does not go away in two days, call your doctor. Other side effects include dry mouth, upset stomach and headache.

Please see important information on the next page.

To learn more about a once-a-week treatment, talk to your doctor about Oncazil or go online at www.oncazil.com or call 1-800-ONCAZIL

Oncazil (strodacazil) 10 mg tablets

KAJ Pharmaceutica

AH 5

ONCAZIL (strodacazil)

This summary contains important information about ONCAZIL ("ON-kah-zeel").
It is not meant to take the place of your doctor's instructions. Read this information carefully before you start taking Oncazil. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about Oncazil.

Oncazil is:
Oncazil is a drug used to treat asthma in adults and children as young as 12 years.

Oncazil will not replace fast-acting inhalers for sudden symptoms. If you get an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks.

Who Should Not Use Oncazil
Oncazil should not be used if:
- you have liver damage
- you have experienced a heart attack or stroke
- you have recently had the flu
- you are pregnant

Medicine Interactions
Tell your doctor if you are taking:
- antibiotics (Oncazil may lose its effectiveness).
- NSAIDs (non-steroidal anti-inflammatories; Advil, Aleve, Motrin) (Can increase the amount of Oncazil in your bloodstream).

Warnings
Heart Valve Damage: Rare but serious heart valve problems have been reported with the use of Oncazil. Generally, these problems begin with a noticeable change in heart rhythm. Notify your doctor immediately if you experience a strange heartbeat pattern, or pain in your chest or down your left arm.

Precautions
Patients with a history of kidney disease should be monitored carefully and placed on the lowest starting dose of Oncazil (see also **Monitoring Requirements**).

Side Effects
Serious but Rare
Heart valve damage has been noted in rare cases (see also Warnings). Other rare but serious side effects include severe cough and chest pain.
Common Side Effects
Other side effects have been reported in those taking Oncazil. These side effects are generally mild or moderate and go away within a few days. These side effects include a temporary skin sensitivity to heat, dry mouth, headache, and upset stomach.

Special Populations
Children
Oncazil has been studied in children as young as twelve years. Children should be given the lowest dosage possible and this dosage should never exceed 100 mg. Patients should be monitored for kidney functioning, as young kidneys may be more sensitive to the effects of Oncazil.
Elderly
Oncazil has not been studied in adults over the age of 65.

Pregnancy
Oncazil should not be used during pregnancy. Animal studies showed that Oncazil may cause abnormal heart rates in infants before and after birth. It is not clear what consequences this may have for the developing fetus. Therefore, Oncazil is not recommended for use in pregnancy. Tell your doctor if you are pregnant or plan to get pregnant.

Clinical Trial Information
What tests were conducted
Oncazil was studied in three large trials with over 10,000 men and women. Oncazil was compared to placebo (pill with no medicine in it) to see if people controlled their symptoms more than without the drug.
How long clinical trials lasted
In two studies, patients took Oncazil for 12 weeks. In the third study, patients were followed for 18 months.

How Long It Takes to Work
Once you take your first pill, Oncazil will begin working immediately. As long as you remember to take a pill at the same time every week, you will not experience any changes in its effectiveness.

Different Dosage Forms
Oncazil is available in a once-a-week and a once-a-day formulation. Talk to your doctor about the best dosing form for you.

Dosing
Your prescription for Oncazil will include up to twelve pills. Choose a time that you can remember each week. At that time, take one tablet with a full glass of water. Take one pill at the same time once a week.
What to do if a Dose is Missed
If you forget to take a pill during the first two days, take it as soon as you remember, record the date, and tell your doctor at your next visit. If you remember after the first two days, do not take it until your normally scheduled time and tell your doctor at your next visit.
Monitoring requirements
Your doctor will give you a simple kidney monitoring test every 4 months while you are taking Oncazil to check for kidney function changes.
Ingredients
Strodacazil, lactose monohydrate, stearic acid, titanium dioxide, red ferric oxide, yellow ferric oxide, carnauba wax.

What to do in the Case of an Overdose
If you take more than the prescribed amount of Oncazil AND experience sharp pains in your chest, call 911 or go to the nearest emergency room.

Abuse Potential
Oncazil has not been shown to be habit-forming or cause withdrawal symptoms.

How Oncazil Works
It is believed that Oncazil changes the function of one of the neurons in the brain that controls respiratory functions.

Lifestyle Factors to Think About When Taking Oncazil
Oncazil will not take the place of fast-acting inhalers for sudden symptoms. In order to benefit the most from taking Oncazil, talk to your doctor about identifying specific asthma triggers that affect you and how to avoid them.

Other Food and Medicines You May Be Taking
Caffeine. Oncazil does not interact with caffeine.
Alcohol. Use caution when drinking alcohol and taking Oncazil. Oncazil may speed up the effects of alcohol.
Herbal supplements. Oncazil is not known to interact with any herbal substances, but tell your doctor if you take any.
Over-the-Counter Drugs. NSAIDS (Advil, Aleve, Motrin) may cause more of Oncazil to build up in your bloodstream, causing an upset stomach.

Other Things to Tell the Doctor
- If you develop a temporary skin sensitivity to heat.
- If you are having trouble remembering to take a pill weekly.
- If you experience any lightheadedness and/or weakness.

Storage
Store Oncazil at room temperature (65-80 degrees F).

General Information about Prescription Drugs
- Only take for what it is prescribed
- Only take as the doctor instructed
- Do not share this prescription with others

Reporting Side Effects
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How to Get More Information
- Talk to your doctor or pharmacist
- Visit www.oncazil.com
- Call 1-800-ONCAZIL

Rx only

10 mg tablets

Oncazil (strodacazil) KAJ Pharmaceutica St. Louis, MO

AH 5

Most Important Risks

- “Fair balance” for print ads
- Specific risk disclosure requirement for broadcast ads; likely to include:
  - Contraindications (relevant to patients)
  - Major warnings, especially if boxed or bolded
  - Significant precautions/drug interactions
  - Frequent side effects

Additional Considerations

- Reasonably comparable communication of risks
  - Consumer-friendly language for both benefits and risk (readability)
  - Prominence of presentation
- Necessary context for claims/risks
- What's needed for informed discussion with health care professional

Specific Disclosure Requirements

- Food, Drug, & Cosmetic Act (502(n)):
  - prescription drug ads must include "information in brief summary relating to side effects, contraindications, and effectiveness"
- Act left specifics to regulations

“Brief Summary”

- Regulations: “Brief summary” information must include “each specific side effect and contraindication”
  - meaning, all risk concepts
- Typical compliance: reprinting risk-related sections of product labeling
  - but, verbatim reprinting not required

“Brief Summary”: Print vs. Broadcast

- Print: little or no flexibility to reduce required information
- Broadcast: media limitations implicitly acknowledged through provision of alternative means of disseminating additional information

Broadcast Advertisement Requirements

- *Must* have information about "major side effects and contraindications"
  - in audio, or audio plus visual
- PLUS can *either*:
  - present brief summary, or
  - make "adequate provision" for disseminating product labeling

Broadcast Advertisement Guidance

- Takes advantage of regulatory flexibility
- Reinforces requirements that ads:
  - must be truthful and not misleading
    - communicate Rx status of product
  - communicate product's indication
  - communicate most important risk information

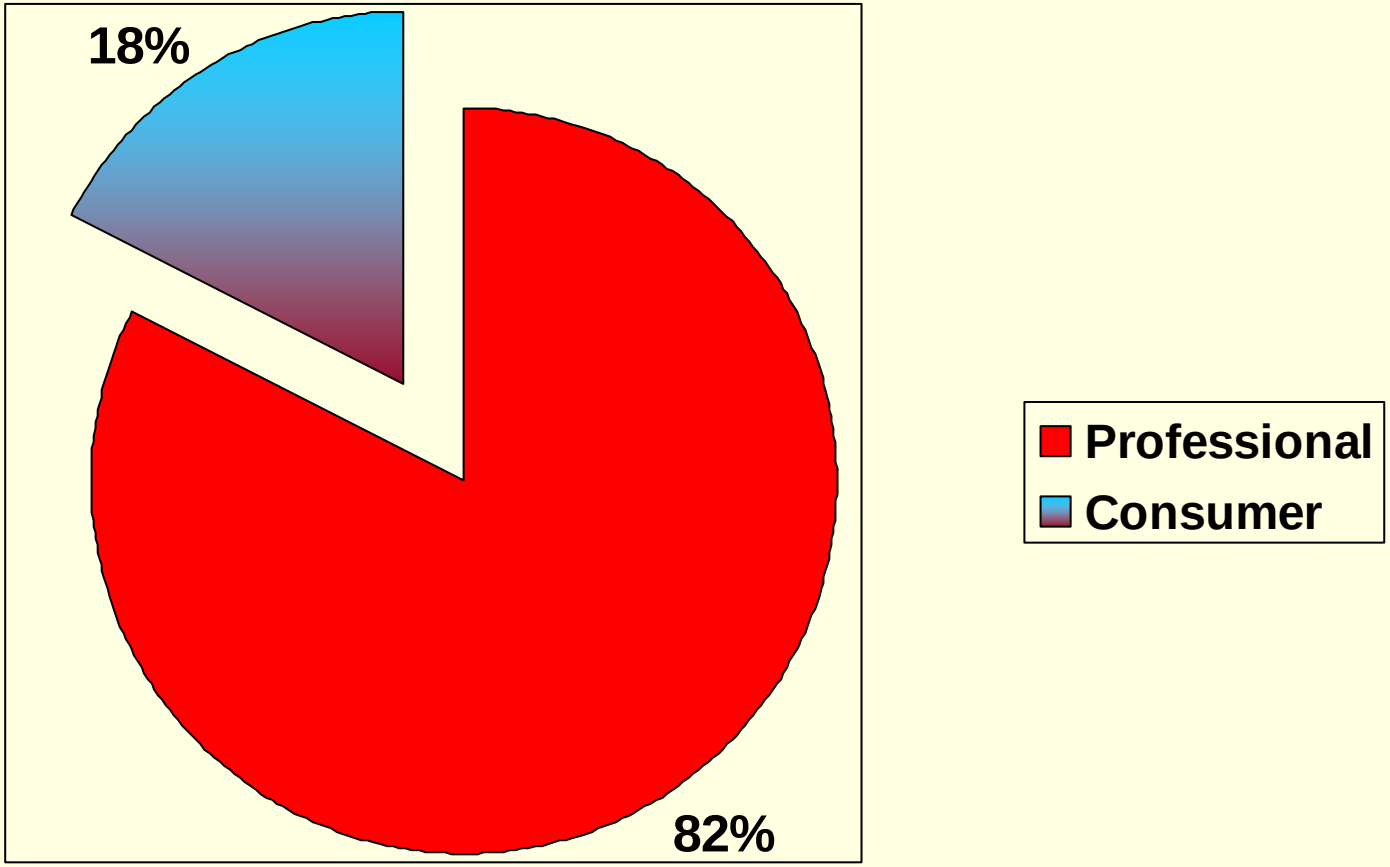
Clarifies "Adequate Provision" for DTC Ads

- One possible, multi-faceted approach to reach *diverse audience* with required product information
  - toll-free phone number for information to be mailed or read
  - concurrently available print information
  - internet address
  - reference to health care provider as source of more product information

Clarification to Some Beliefs

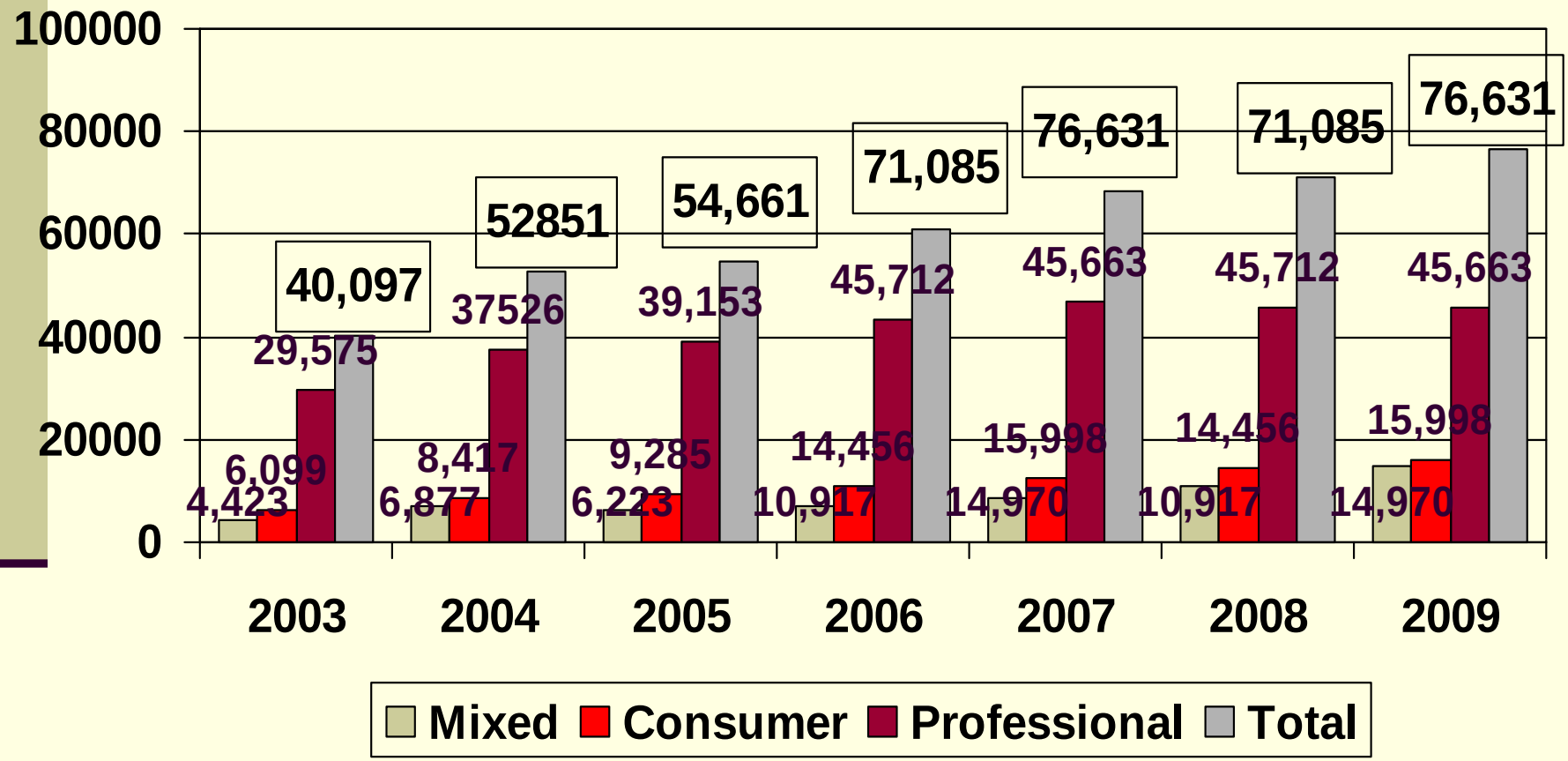
- No laws or regulations ever prohibited promoting prescription drugs to consumers (in general or for specific products or drug classes)
- Regulatory focus is on the content of the materials NOT their general existence or the amount of promotion

2008 Promotional Spending: Professional versus Consumer



Source: IMS Health, Integrated Promotional ServicesTM, year 2008, Data Extracted July 2009.

of Final Promotional Pieces Submitted (2253s) 2003 - 2009



The Evolution of Direct-to-Consumer Prescription Drug Advertising

If the law allowed ads to be directed to consumers, why didn’t we see them until relatively recently?

Evolution of Direct-to-Consumer (DTC) Advertising

- Up to 1980s: consumer communications controlled through "learned intermediary"
- 1980's: First DTC ads and fallout

  --1983-1985: FDA voluntary moratorium

  --1985: moratorium lifted, regulations provide "sufficient safeguards to protect consumers"
- 1990s: increase in print ads
- Mid 1990s: broadcast ads enter mix

Why did DTC become important?

- Consumer empowerment
  - desire for more involvement in own care
  - consumers actively seeking information
- Aging baby-boomer population
  - caring for selves, children, parents
- Managed Care
- Sponsors' marketing strategy

Early Broadcast Environment: Before 1996

- Static -- sponsor uncertainty regarding requirement for “brief summary”
- “Adequate provision” for providing labeling always allowed
  - Adequate provision not defined in regulation
- Major risks required to be disclosed regardless of path chosen

Result:

A broadcast environment dominated by reminder advertising

Risk Disclosure for Broadcast Ads

- Broadcast ads need:
  - **most important** risks disclosed in ad itself in audio or audio and video: aka, the “major statement”
  - AND
  - access to either **all** risks or “adequate provision” for disseminating product labeling (PI)

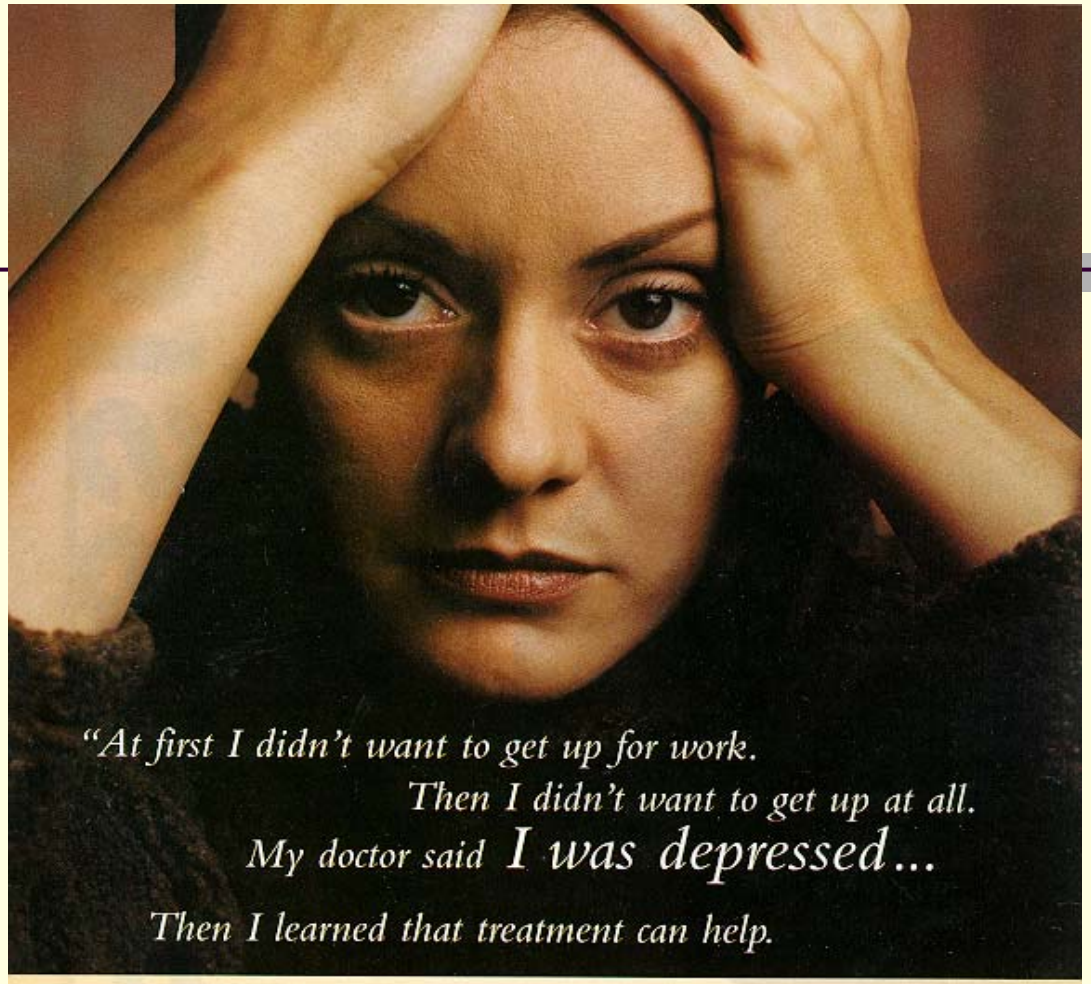
Addressing “Adequate Provision”

- How to reach diverse group of consumers?
  - sponsors had some suggestions
- 1997 draft guidance; 1999 final guidance
  - reference to health care provider
  - print ads/brochures
  - telephone contact number
  - internet site
- Reinforces underlying requirements
- Encourages consumer-friendly information

Examples of Direct-to-Consumer Advertising

Examples of DTC Promotion

- Help-Seeking
  - disease discussion … “see your doctor”... consistently encouraged, important for under-diagnosed, under-treated health conditions
  - not drug ads, so not covered by FD&C Act
  - draft guidance clarifies FDA’s position on these types of ads



Now, I'm feeling better."

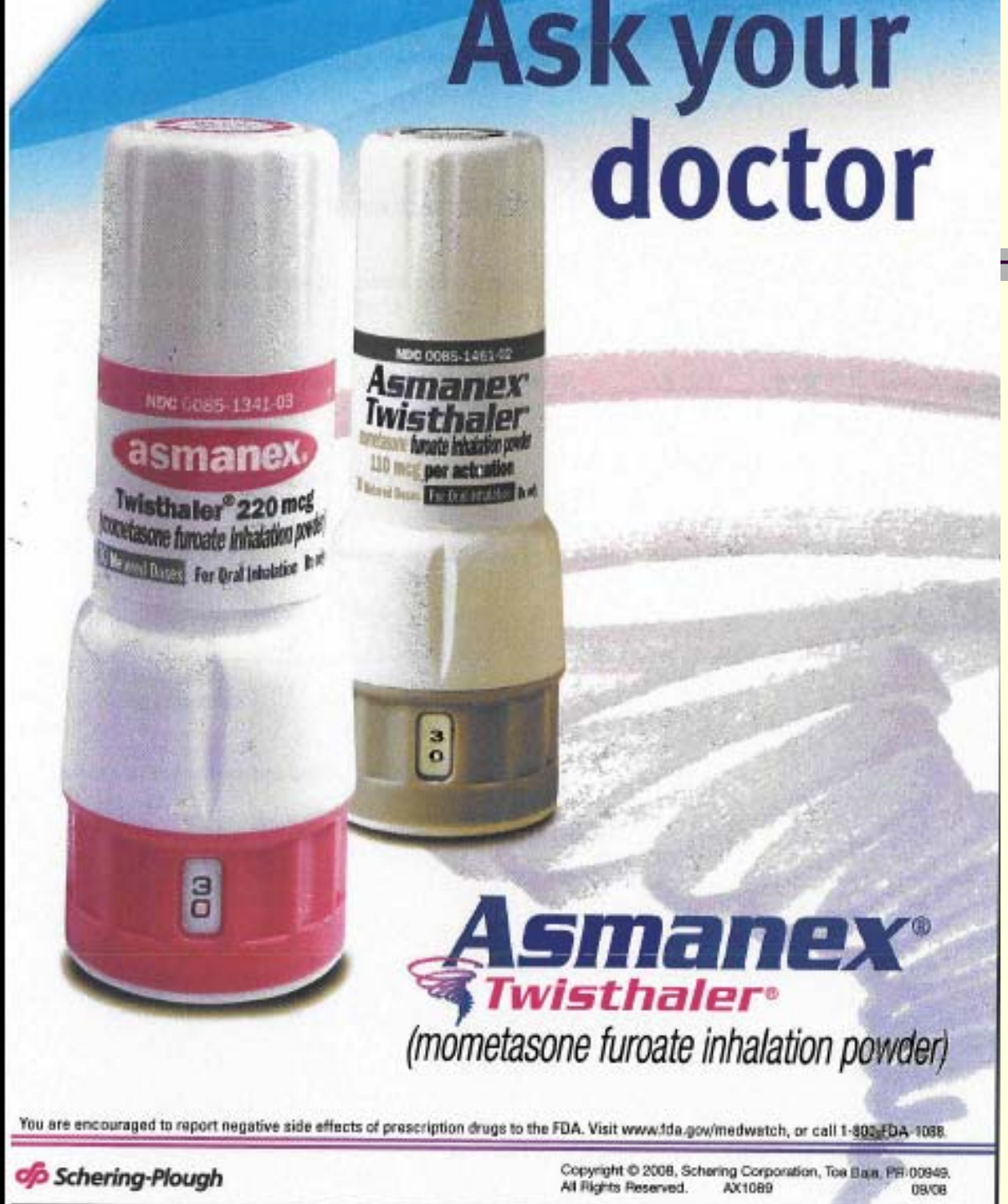
About 1 in 6 Americans will experience depression in their lifetimes. Depression is a condition that can affect people's jobs, families, and lives. But there is hope. Treatment is available—psychological therapy and antidepressant medicines are among the options that can help relieve depression. In fact, it has been shown that most people who receive treatment improve. Through patient education and research and development of drug therapies, Pfizer is helping millions of people realize that depression can be overcome.

If you'd like to learn more about depression, please call your doctor. For free, confidential brochures about depression, its symptoms, and its treatment, please call: **1-888-549-9422**.
www.depression-info.com

Life is our life's work Pfizer

Examples of DTC Promotion

- Reminder ads/labeling
  - exempted from risk disclosure requirements
  - includes product name, but no representations beyond dosage form, packaging, price info
  - not allowed for products with boxed warnings


Ask your doctor
NDC 0085-1341-03
asmanex
Twisthaler® 220 mcg
mometasone furoate inhalation powder
For Oral Inhalation
30
NDC 0085-1461-02
Asmanex
Twisthaler
mometasone furoate inhalation powder
220 mcg per actuation
For Oral Inhalation
30
Asmanex®
Twisthaler®
(mometasone furoate inhalation powder)
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.
Schering-Plough
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Examples of DTC Promotion

- Product claim
  - claims or representations trigger disclosure requirements for accuracy and balance
  - risk disclosure requirements
    - Body of promotional piece
      - Usually the most serious risks and most common adverse events
    - Brief summary or full product labeling must be included
      - “brief summary” for print ads
      - “adequate provision” for broadcast ads
      - full product labeling for promotional labeling

Oversight Program for DTC

- Voluntary Compliance
  - Advisory comments
  - Guidance documents
  - Educational efforts
    - Outreach
    - Website
- Comprehensive surveillance and enforcement program

Continuing Evolution of DTC

- Major Guidance Development
  - Broadcast ads (“Adequate Provision”) (1997 & 1999)
  - Brief Summary Alternatives (2004)
  - Help-Seeking Communications (2004)
  - Presentation of Risk Information (2009)
- FDAAA – Title IX (Sept 2007)
  - First law to specifically address DTC

DDMAC Regulatory Enforcement

Enforcement

- Untitled letters (Notice of Violation/NOV)
- Warning letters
- Injunction/consent decree
- Seizures
- Criminal action
- Civil monetary penalties

Common Violations

- Inadequate communication of risk info
  - Missing content
  - Presentation (minimization, comparability)
- Misleading communication of indication
  - Promoting beyond the indicated population or beyond the indication of the drug
- Misleading product efficacy claims
  - Overstatement of efficacy

Examples of Violative Advertisements

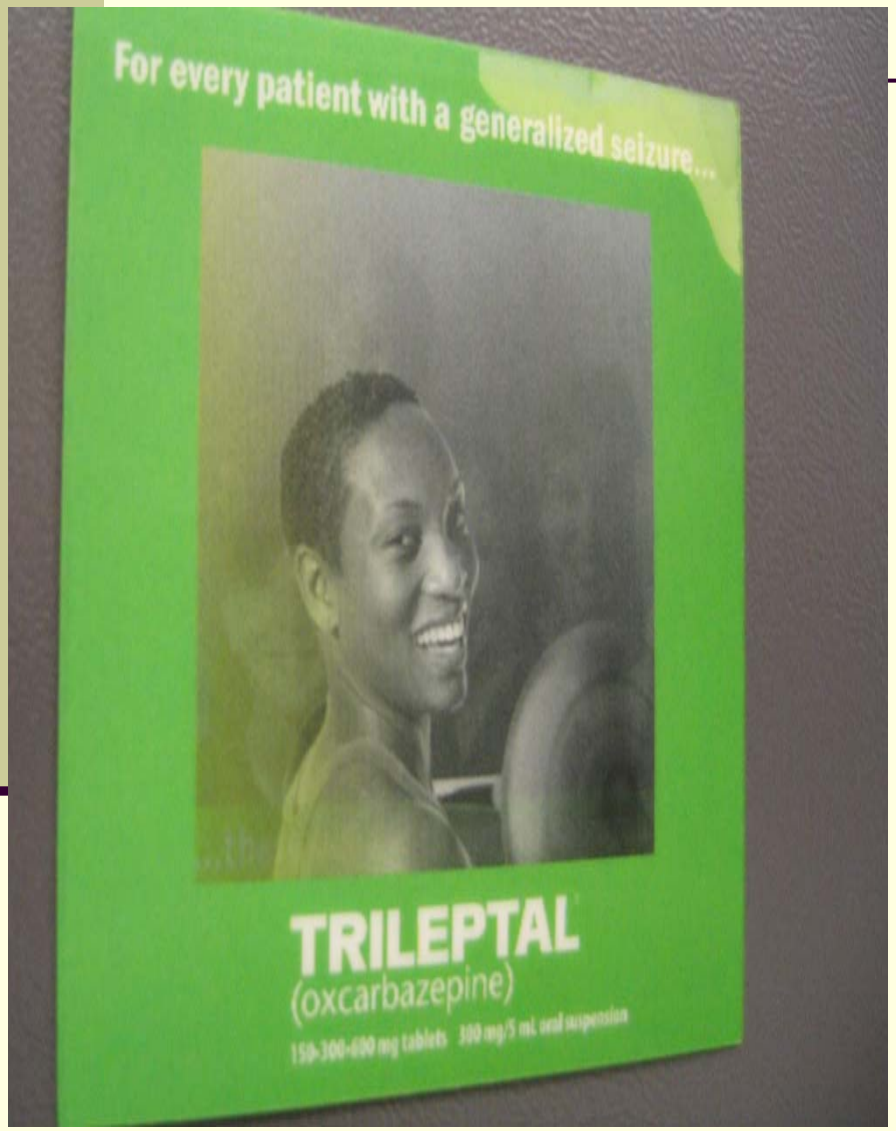
“Reminder Ad” for Buproprion ER

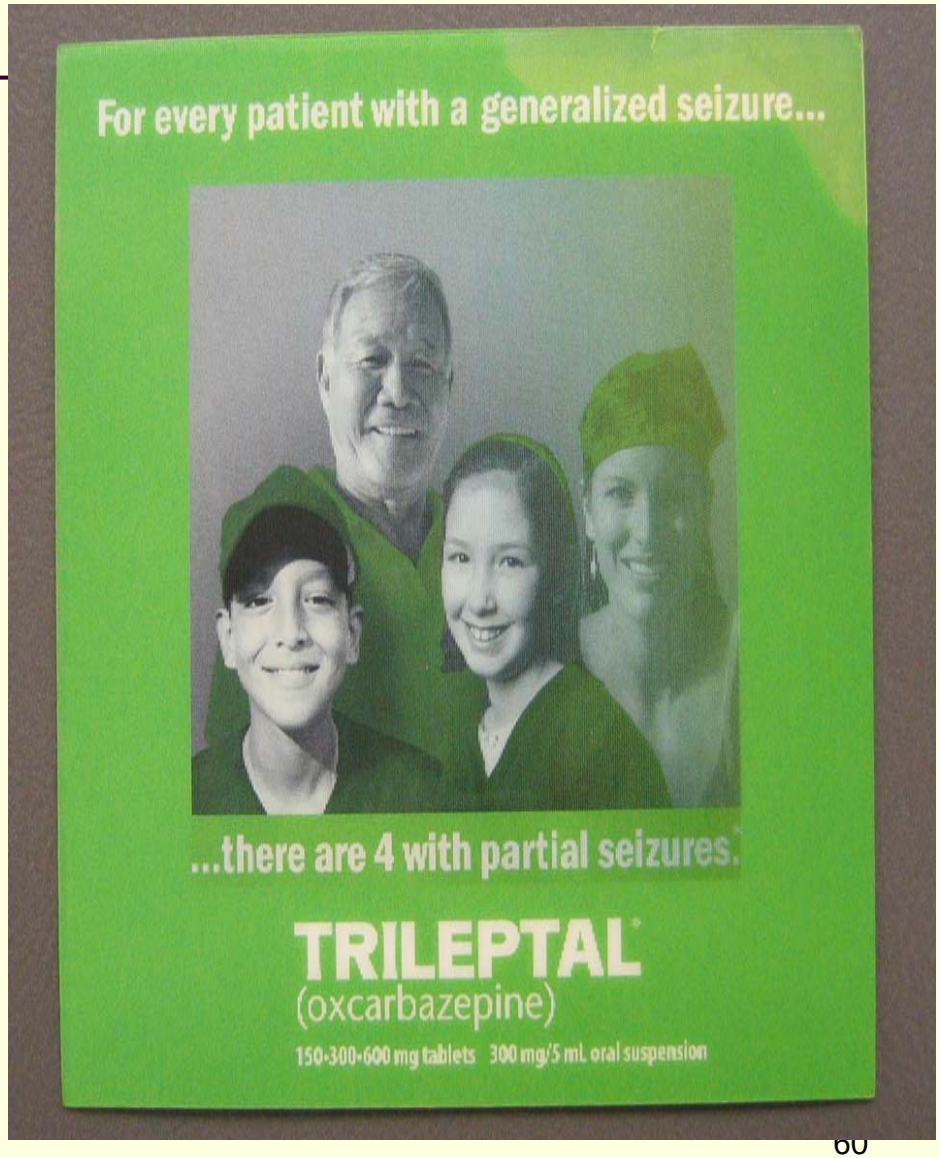
- NOV issued for this “impermissible reminder ad”
- "Reminder advertisements. . . are not permitted for a prescription drug product whose labeling contains a boxed warning relating to a serious hazard associated with the use of the drug product."
- Labeling contains a boxed warning
- Ad fails to present brief summary

Viagra “Reminder” TV Ad

- Makes representations about Viagra
- Approved indication not presented
- No risk information, no adequate provision
- Overstates efficacy of product

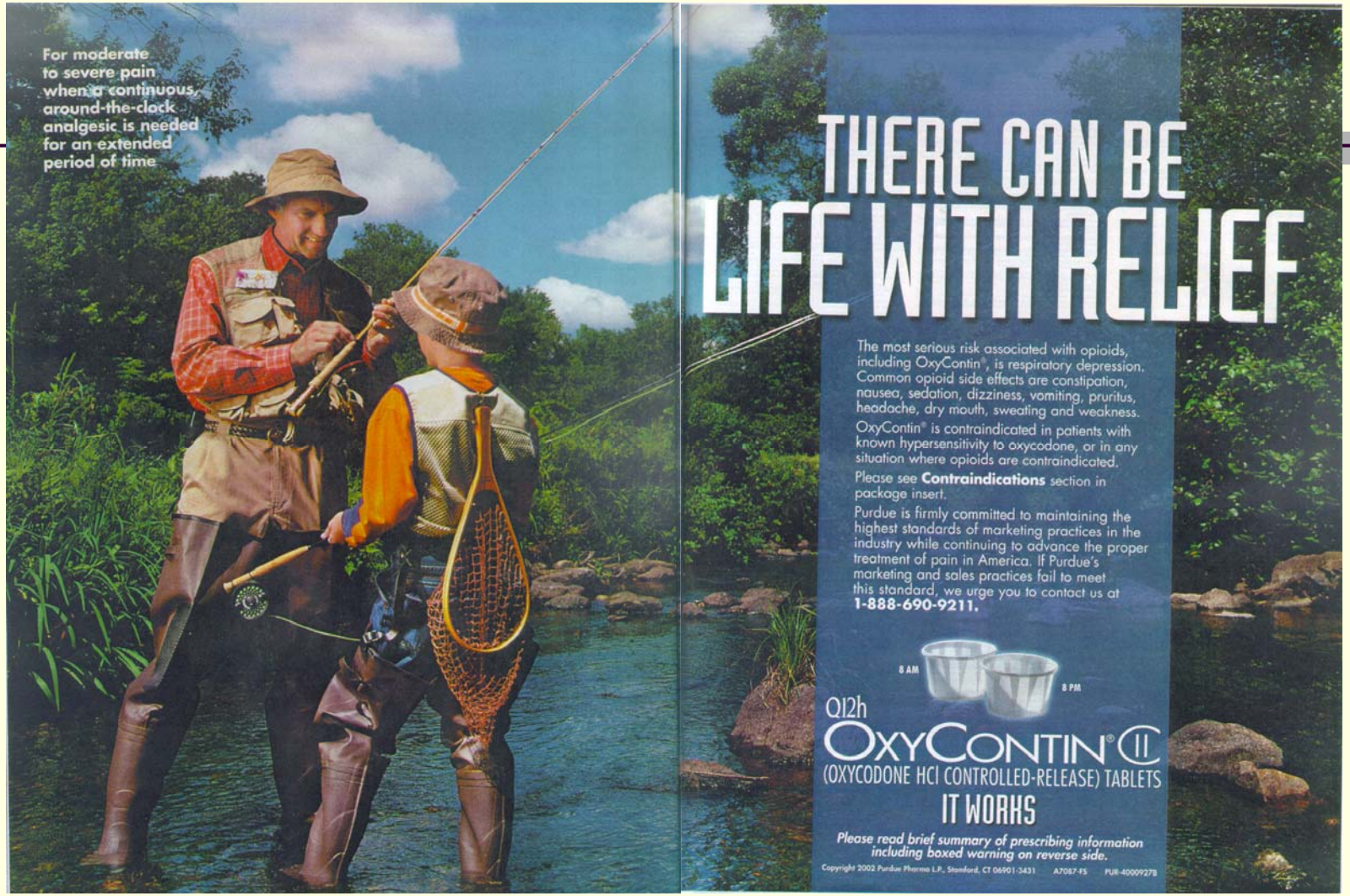
Lenticular Magnet for Trileptal





Trileptal - Magnet

- Omission of indication and risk information
  - Effectiveness claims presented, but indication and risk are not
    - (Included on back of magnet--as a practical matter, this information is not communicated)
    - Magnet is designed to adhere to magnet surfaces—once displayed, content on back is not visible
- Encourages use in circumstances other than those for which shown to be safe and effective
  - Implies drug is indicated for generalized seizures
    - Full indication is not presented on front of magnet
    - Especially problematic in the view where only generalized seizures claim is visible


For moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time
THERE CAN BE LIFE WITH RELIEF
The most serious risk associated with opioids, including OxyContin®, is respiratory depression. Common opioid side effects are constipation, nausea, sedation, dizziness, vomiting, pruritus, headache, dry mouth, sweating and weakness.
OxyContin® is contraindicated in patients with known hypersensitivity to oxycodone, or in any situation where opioids are contraindicated.
Please see Contraindications section in package insert.
Purdue is firmly committed to maintaining the highest standards of marketing practices in the industry while continuing to advance the proper treatment of pain in America. If Purdue's marketing and sales practices fail to meet this standard, we urge you to contact us at 1-888-690-9211.
8 AM
8 PM
Q12h
OXYCONTIN® CII
(OXYCODONE HCl CONTROLLED-RELEASE) TABLETS
IT WORKS
Please read brief summary of prescribing information including boxed warning on reverse side.
Copyright 2002 Purdue Pharma L.P., Stamford, CT 06901-3431 A7087-FS PUR-40009278

OxyContin Journal Ad

- No risk information from the boxed warning (e.g., abuse liability and potentially fatal risks due to formulation) included in the body of the ads
- Minimization of other risk information
- Broadening of Indication/Failure to communicate limitations on indication
- Serious public health concerns
- Corrective advertisement requested

Corrective Advertisements

Enbrel TV Ad

2005 WL

Overstatement of Efficacy – there is no evidence that Enbrel provides complete clearing of the psoriasis as demonstrated by the models

- "tell psoriasis where to get off – Enbrel"
- - the super mentions, "results may vary" which is not sufficient
- - unsubstantiated claim: "Enbrel is a breakthrough" when no significant advantage has been shown over drugs for this condition
- - misleading onset claim: "dramatically clear skin fast" (consumers may not interpret this as 2 months)

Misleading Communication of the Limits to the Indication

- - broadens the indication – this drug is indicated for moderate to severe psoriasis

Minimization of Risk

- - the major statement is minimized by distracting visuals, fast-paced graphics/supers

Yaz TV Ad

- Broadening of indication
  - Symptoms in these ads are commonly seen in women with PMS, which is a disorder that is less serious and more common condition than PMDD
  - Acne: PI – Yaz treats moderate acne only
- Overstatement of efficacy
  - “Goodbye to you” and kicking away balloons —PI says that patients experienced a decrease (improvement) in PMDD symptoms, not elimination of symptoms
  - Acne: Again, elimination of symptoms—clear skin, goodbye to you, balloons disappearing
- Minimization of risk
  - Distracting visuals
  - Numerous scene changes
  - Background music

DDMAC Policy Development, Advice and Surveillance Programs

Policy Development

- Draft Guidance on Presentation of Risk Information
- Research on Brief Summary leading to revised draft guidance
- Future areas for guidance development
  - e.g., Internet guidance including social media
- Implementation of FDAAA provisions

Advice to Industry

- Provide comments on DRAFT promotional materials (VOLUNTARY in most cases)
  - Launch materials for new drugs or new indications
  - Direct-to-consumer (DTC) broadcast ads
  - Non-launch materials
- Pre-submission required for certain drugs
  (e.g., Subpart H/Subpart E “accelerated approval”)
- Technical assistance on Social Science research studies

Advice within FDA

- Provide consultation on:
  - Draft labeling
  - Cartons and product labels
  - Medication Guides
  - Patient Package Inserts (PPIs)
  - Dear Healthcare Provider letters
  - Pharmacoeconomics, health-related patient-reported outcome protocols
  - Social Science research studies

Surveillance

- Review materials submitted to DDMAC at the time of initial dissemination (Form 2253)
- Conferences
- Complaints
  - Healthcare professionals
  - Consumers
  - Competitors

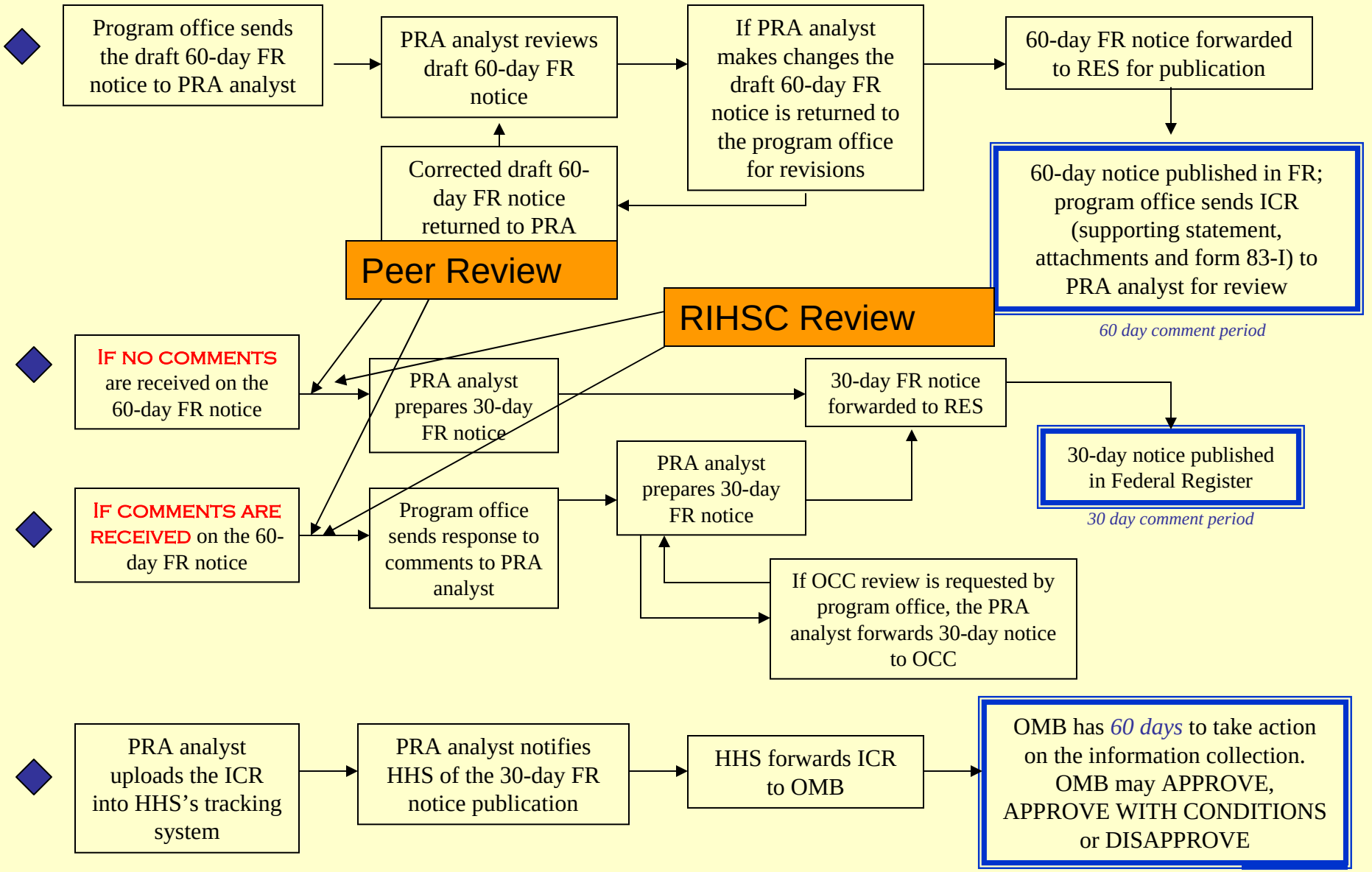
DDMAC Research Program

Research Focus

- Informed Decision Making
- Risk Communication
- Enforcement

OMB Information Collections

Flow of Federal Register Notices for Public Comment



Informed Decision Making Studies

- Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Broadcast Advertisements*
- Drug Risk/Benefit Analysis in Variations of Display Pages of Print Direct-to-Consumer Prescription Drug Advertisements
- Presentation of Quantitative Information about Benefits and Risks in DTC Ads
- Toll-Free Number for Reporting Side Effects in DTC Television Ads

*With Nancy Ostrove, (FDA, Office of the Commissioner) and
Scott Douglas (HHS, Office of the Assistant Secretary for Planning and Evaluation)

FDA

Informed Decision Making Studies, continued

- Disease Awareness Information in Branded Promotional Material
- Examination of Online Direct-to-Consumer Promotion
- Focus Groups to Investigate Consumer and Physician Beliefs about Direct-to-Consumer (DTC) Advertising

Risk Communication Studies

- Variations in the Brief Summary in Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs: Use, Content and Format
- Experimental Study of Format Variations in the Brief Summary of Direct-to-Consumer (DTC) Print Advertisements
- Impact of Incentives Embedded in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Perceptions of Product Risks and Benefits

Enforcement Studies

- Copy Testing of individual advertisements

Questions?

Online DDMAC Information

- DDMAC home page: http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm
- Warning and untitled letters: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/default.htm
- Guidances: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

- Phone number: (301) 796-1200
- Fax numbers: (301) 847-8444 and (301) 847-8445
- My contact info: kathryn.aikin at fda.hhs.gov